

U.S. Patent Application Serial No. **10/535,422**  
Amendment filed May 30, 2008  
Reply to OA dated March 7, 2008

### **REMARKS**

Claims 1-17 are pending in this application. Claim 1 is amended, and claims 18 and 19 are newly added herein. Upon entry of this amendment, claims 1-19 will be pending. Entry of this amendment and reconsideration of the rejections are respectfully requested.

No new matter has been introduced by this Amendment. Support for the amendment to claim 1 that the stainless steel is "substantially free of Ni" may be found in paragraphs [0005] and [0015] of the specification. Example 1 in paragraph [0040] can also be seen to be prepared without added Ni, and therefore to be substantially free of Ni.

Support for new claim 18, reciting that the "working step comprises forming a metal tube of thickness 50 to 400  $\mu\text{m}$ ," may be found in paragraph [0027]. Support for the recitation of claim 19, that the metal tube is used for a stent, may be found in the first embodiment of the invention.

**Claims 1-17 are rejected under 35 U.S.C. §103(a) as being unpatentable over Berns (U.S. Patent No. 5,503,687) in view of Speidel et al. (U.S. Patent No. 5,714,115).** (Office action paragraph no. 1)

Reconsideration of the rejection is respectfully requested in view of the amendments to claim 1.

Claim 1 has been amended to recite that the stainless steel is "substantially free of Ni." Berns is cited for disclosing a ferritic stainless steel, However, the stainless steel of Berns shown in Fig.

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1 has 12% Ni, and the stainless steel of Berns in Fig. 2 has 5% Ni. The combination of these stainless steels of Berns with Speidel would not meet the limitations of claim 1, as amended.

Applicant further argues that the present claims are non-obvious over the combination of Berns and Speidel, for the following reasons.

While Berns describes the invention forming the austenite containing Ni (refer to FIG. 3 of Berns), the present invention is characterized by transforming into austenite **from ferrite without Ni**. The present invention is biocompatible due to the **Ni-free** characteristics. Furthermore, since the present invention uses steel transformed to austenite from ferrite, mechanical strengthening is possible after processing into fine structure.

Also, Berns describes that "the martensitic of ferritic structure portions in the surface zone are converted to austenite" (Berns, column 1, lines 38 to 40). In contrast, the present invention transforms at least part of ferritic stainless steel to austenite.

That is, the invention described in Berns is formed by austenite or martensite on the surface, therefore the workability is inferior (harder) compared to the present invention, and therefore preparing a medical device having fine structure as described in the present invention would be difficult with the invention described in Berns. That is, the present invention and Berns differ in their compositions. Moreover the effect of the present invention is unexpected over the cited art.

Thus, even though Speidel discloses a stainless steel medical device for human body (Speidel, claim 9), it would not have been obvious to attain the present invention from invention described in Berns.

In support of this argument, Applicant refers to the following table for the general characteristics of the stainless steels.

Name of structure	Ferrite	Martensite	Austenite
workability	Least hard	Most hard	intermediate hardness
	Least fragile	Most fragile	intermediate fragility
	therefore, has good workability	therefore, has poor workability	therefore, has intermediate workability
	poseses magnetic properties	poseses magnetic properties	No magnetic properties
Note	It can form this structure easily without Ni	It is hard to form this structure without Ni	It is hard to form this structure without Ni

- Transforming into austenite from ferrite

An austenite is a preferable structure for a device since it possesses good balance between hardness and fragility. Also, since it does not possess magnetic properties, it is unlikely to cause adverse effect when it is placed within the body. However, since austenite is slightly hard and fragile, fine processing of austenite itself is difficult.

On the other hand, a ferrite is most suitable for fine processing since it is least hard and least fragile. However, ferrite cannot be used in items that require strength, since it is too flexible to be

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used as a device. Also, ferrite is likely to cause adverse effect when it is placed within the body since it possesses magnetic properties.

- Austenite structure without Ni (present invention)

In order to obtain austenite structure, those who manufacture the metal alloy will usually include Ni in the metal alloy since Ni is capable of accelerating the formation of austenite structure. However, Ni is liable to cause allergic reaction in the body.

The present invention is able to provide a device having austenite structure without Ni, therefore the risk of allergic reaction is lowered. Also, it does not possess magnetic properties. Furthermore, since the present invention is in ferrite structure during the working steps, fine processing is possible.

Thus, a finely processed medical instrument substantially free of Ni is possible according to the present invention. Applicant submits that the pending claims are not obvious over Berns and Speidel, taken separately or in combination.

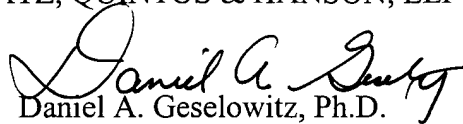
If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact the applicant's undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

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In the event that this paper is not timely filed, the applicant respectfully petitions for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

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